

**6.12 TIOTROPIUM,
Solution for oral inhalation 2.5 micrograms (as
bromide monohydrate) per actuation (60 actuations),
Spiriva® Respimat®,
Boehringer Ingelheim Pty Ltd**

1 Purpose of Application

- 1.1 The minor submission provided notification that the existing presentation of tiotropium solution for oral inhalation that has a non-reusable inhaler device is to be discontinued/phased out in early 2021 and replaced with (i) a presentation with a re-usable inhaler with dose counter and (ii) a presentation containing just the cartridge refill without the inhaler device. No changes to the listed drug were otherwise proposed.

2 Background

- 2.1 Currently, Spiriva® Respimat® is formulated as a clear, colourless solution and stored inside an aluminium cylinder (cartridge) for use with the Respimat inhaler. Each pack consists of one Spiriva Respimat inhaler and one cartridge, delivering 60 metered actuations. The current Spiriva Respimat inhaler can only be used with a single cartridge. Once the cartridge is depleted, the Spiriva Respimat inhaler is irreversibly locked and cannot be removed; and is thus non-reusable. For ease of reference, the current Spiriva Respimat product will be referred to as the Spiriva Respimat disposable inhaler for these meeting minutes and the new presentation (both single pack and single refill pack) will be referred to as Spiriva Respimat re-usable inhaler.
- 2.2 Spiriva Respimat disposable inhaler is currently listed on the PBS as a Restricted Benefit for the long-term maintenance treatment of Chronic Obstructive Pulmonary Disease (COPD) (PBS item code 10509D) and for the treatment of severe asthma in adults (PBS item code 11043F). Spiriva Respimat disposable inhaler is also currently listed on the PBS as an Authority Required (STREAMLINED) listing for severe asthma in children aged six to 17 years old (PBS item code 11629C).
- 2.3 The submission stated that only device components that are not in contact with the inhalation solution and have no impact on the performance parameters of the Spiriva Respimat re-usable inhaler had been modified to allow the inhaler to be re-usable as well as improve patient handling and usability. The device components changed include the:
- dose indicator - enlarged in size and now attached to the cartridge instead of the Spiriva Respimat inhaler;

Public Summary Document – July 2020 PBAC Meeting

- reversible device lock – changed from irreversible to reversible in order to enable the Spiriva Respimat inhaler to be re-usable. The Spiriva Respimat re-usable inhaler is recommended for use with up to six cartridges, which allows patients to use the same inhaler for up to six months.

2.4 Assuming a PBS listing date of 1st March 2021, the submission stated that wholesalers will cease supply of the Spiriva Respimat disposable inhaler effective 1st March 2021. The submission stated only the Spiriva Respimat re-usable inhaler (both single pack and single refill pack) will be able to be distributed from 1st March 2021.

Registration status

2.5 Spiriva Respimat re-usable inhaler was TGA registered on 2nd March 2020 for the same indications as those of Spiriva Respimat disposable inhaler.

2.6 The TGA Approval Letter dated 2 March 2020 stated that, while Spiriva Respimat re-usable inhaler is a separate and distinct good under subsection 16(1) of the Act, it is the same as the currently registered Spiriva Respimat disposable inhaler except for a new container type with dose indicator for use with the dedicated inhaler device provided as a procedure pack.

For more detail on PBAC’s view, see section 6 PBAC outcome.

3 Requested listing

3.1 The submission requested the supply of Spiriva Respimat disposable and Spiriva Respimat re-usable inhaler (both the pack that contains the re-usable inhaler and the pack that contains the refill cartridge only) under the existing PBS item code for Spiriva Respimat without the addition of 2 new trade product packs to differentiate the 3 presentations on the PBS schedule. This was the submission’s preferred option. This alternative option was to add 1 new PBS item code (1 new code for the refill cartridge). The Secretariat proposed 3 separate codes and to mark all 3 presentations equivalent for the purposes of substitution (a-flag) as outlined below.

3.2 The option of PBS listing with two additional PBS item codes and ‘a’ flagging:

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Dispensed Price max. qty	Proprietary Name and Manufacturer	
TIOTROPIUM							
tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations	10509D	1	1	5	\$42.47	Spiriva Respimat	Boehringer Ingelheim Pty Ltd
tiotropium 2.5 microgram/actuation inhalation solution inhaler and cartridge, 60 actuations	NEW	1	1	5	\$42.47	Spiriva Respimat	
tiotropium 2.5 microgram/actuation inhalation solution cartridge, 60 actuations	NEW	1	1	5	\$42.47	Spiriva Respimat	

Public Summary Document – July 2020 PBAC Meeting

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
Restriction type: <input checked="" type="checkbox"/> Restricted benefit
Indication: Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease
Treatment Phase: Long-term maintenance treatment
Administrative Advice: The treatment must not be used in combination with a LAMA/LABA or SAMA
Administrative Advice: A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.
Administrative Advice: A SAMA includes ipratropium
Administrative Advice: Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
Administrative Advice: Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.
Administrative Advice: <i>Pharmaceutical benefits that have the form tiotropium 2.5 microgram/actuation inhalation solution and tiotropium 2.5 microgram/actuation inhalation solution inhaler and cartridge and pharmaceutical benefits that have the form tiotropium 2.5 microgram/actuation inhalation solution cartridge are equivalent for the purposes of substitution.</i>

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Dispensed Price max. qty	Proprietary Name and Manufacturer	
TIOTROPIUM							
tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations	11043F	1	1	5	\$42.47	Spiriva Respimat	Boehringer Ingelheim Pty Ltd
tiotropium 2.5 microgram/actuation inhalation solution inhaler and cartridge, 60 actuations	NEW	1	1	5	\$42.47	Spiriva Respimat	
tiotropium 2.5 microgram/actuation inhalation solution cartridge, 60 actuations	NEW	1	1	5	\$42.47	Spiriva Respimat	

Public Summary Document – July 2020 PBAC Meeting

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
Restriction type: <input checked="" type="checkbox"/> Restricted benefit
Indication: severe asthma
Clinical criteria: Patient must have experienced at least one severe exacerbation, which has required documented use of systemic corticosteroids, in the previous 12 months while receiving optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented
AND
Clinical criteria: The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.
AND
Population criteria Patient must be aged 18 years or older.
Prescribing instructions: Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.
Administrative Advice: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).
Administrative Advice: <i>Pharmaceutical benefits that have the form tiotropium 2.5 microgram/actuation inhalation solution and tiotropium 2.5 microgram/actuation inhalation solution inhaler and cartridge and pharmaceutical benefits that have the form tiotropium 2.5 microgram/actuation inhalation solution cartridge are equivalent for the purposes of substitution.</i>

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Dispensed Price Max. Qty	Proprietary Name and Manufacturer
TIOTROPIUM						
tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations	11629C	1	1	5	\$42.47	Spiriva Respimat
tiotropium 2.5 microgram/actuation inhalation solution inhaler and cartridge, 60 actuations	NEW	1	1	5	\$42.47	Spiriva Respimat
tiotropium 2.5 microgram/actuation inhalation solution cartridge, 60 actuations	NEW	1	1	5	\$42.47	Spiriva Respimat
						Boehringer Ingelheim Pty Ltd

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction type / Method: <input checked="" type="checkbox"/> Authority Required - Streamlined
Indication: severe asthma
Clinical criteria: Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented.
AND
Clinical criteria:

Public Summary Document – July 2020 PBAC Meeting

Patient must have experienced at least one severe exacerbation prior to receiving PBS-subsidised treatment with this drug for this condition, which has required documented use of systemic corticosteroids in the previous 12 months while receiving optimised asthma therapy; or
Patient must have experienced frequent episodes of moderate asthma exacerbations prior to receiving PBS-subsidised treatment with this drug for this condition.
AND
Clinical criteria:
The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.
Treatment criteria
Must be treated by a respiratory physician, paediatric respiratory physician, clinical immunologist, allergist, paediatrician or general physician experienced in the management of patients with severe asthma; or in consultation with one of these specialists.
Population criteria
Patient must be aged 6 to 17 years inclusive.
Prescribing instructions: Optimised asthma therapy includes adherence to the maintenance combination of a medium to high dose ICS and a LABA. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative.
Administrative Advice:
Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).
Administrative Advice:
Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners
Administrative Advice:
<i>Pharmaceutical benefits that have the form tiotropium 2.5 microgram/actuation inhalation solution and pharmaceutical benefits that have the form tiotropium 2.5 microgram/actuation inhalation solution inhaler and cartridge and pharmaceutical benefits that have the form tiotropium 2.5 microgram/actuation inhalation solution cartridge are equivalent for the purposes of substitution.</i>

For more detail on PBAC's view, see section 6 PBAC outcome.

4 Comparator

- 4.1 The submission did not nominate a comparator. However, the submission proposed a new re-usable inhaler presentation of tiotropium solution for oral inhalation (Spiriva Respimat re-usable inhaler), and compared this to the currently listed Spiriva Respimat disposable inhaler of the same drug.

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item as it was a minor submission.

Consumer comments

5.2 The PBAC noted and welcomed the input from individuals (1), health care professionals (1), and organisations (2) via the Consumer Comments facility on the PBS website. The comments from the Lung Foundation and Asthma Australia described a range of benefits of treatment with the Spiriva Respimat re-usable inhaler including the ease-of-use and the reduced environmental footprint.

Clinical trials

5.3 As a minor submission, no clinical trials were presented in the submission.

Drug cost/patient/year: \$509.64

5.4 The submission stated the approved ex-manufacturer price of the Spiriva Respimat re-usable (both single pack and single refill pack) would be the same as the current Spiriva Respimat disposable inhaler (AEMP \$28.82).

5.5 The estimated drug cost per patient per year for Spiriva Respimat re-usable inhaler was \$509.64 based on the proposed dispensed price for maximum quantity (DPMQ \$42.47) and 12 scripts per year.

Estimated PBS usage & financial implications

5.6 The minor submission estimated there to be no financial implications to the PBS or changes in PBS usage as the submission expected Spiriva Respimat re-usable inhaler to only substitute for Spiriva Respimat disposable inhaler and both forms of tiotropium have the same price.

5.7 Although not a matter for the PBAC, the addition of two listings of the same drug/combination item to the Listing Instrument may have pricing implications under Division 3A of the National Health Act 1953.

Quality Use of Medicines

5.8 The submission stated a number of quality use of medicines activities were planned prior to PBS listing to inform healthcare professionals including prescribers, practice nurses and pharmacists of the change from Spiriva Respimat disposable to re-usable.

For more detail on PBAC's view, see section 6 PBAC outcome.

6 PBAC Outcome

6.1 The PBAC held no objections to the planned discontinuation of the existing Spiriva Respimat product and its replacement with an updated product whereby the inhaler device would be re-usable (for up to six cartridges) and the dose counter would be located on the cartridge rather than the inhaler device.

6.2 The PBAC noted the submission proposed the approved ex-manufacturer price

(AEMP) of the Spiriva Respimat re-usable (both single pack and single refill pack) be the same as the currently listed Spiriva Respimat disposable inhaler AEMP.

- 6.3 The PBAC considered that due to the different contents of the proposed products (one with inhaler and one without), it would be helpful to have them distinguished in the Schedule for clarity for patients, prescribers and pharmacists. However, the PBAC noted that the Department would take into consideration Australian Medicines Terminology, pharmaceutical item descriptions appearing in the legislative instruments and software vendor requirements before finalising the details of any new listings on the PBS.
- 6.4 The PBAC noted that no changes to the PBS eligibility criteria for the existing three Spiriva Respimat listings were proposed.
- 6.5 The PBAC advised, under Section 101 (4AACD) of the National Health Act, should it be determined that new trade products be declared as available brands, that Spiriva Respimat re-usable inhaler (both single pack and single refill pack) and Spiriva Respimat disposable inhaler be considered equivalent for the purposes of substitution (i.e., 'a' flagged) to ensure a smooth transition from the existing product to the updated product. An administrative NOTE could be added to request that healthcare professionals ensure patients understand to use the cartridges with the correct device for the particular cartridge.
- 6.6 The PBAC noted the intention of the sponsor to delist Spiriva Respimat disposable inhaler from 1st March 2021, and considered that a formal request to delist Spiriva Respimat disposable inhaler would be required.
- 6.7 The PBAC advised of no change to current nurse practitioner prescribing status.
- 6.8 The PBAC advised of no change to the Early Supply Rule status currently applying.
- 6.9 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

To be finalised.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not

necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.